Remarks

Claims 25, 27, 28, and 32-46 were pending in the subject application. By this Amendment, claims 25, 32, and 45 have been amended, claims 33-35, 37-44, and 46 have been cancelled, and new claims 47-51 have been added. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 25, 27, 28, 32, 36, 45, and 47-51 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Submitted herewith is a Request for Continued Examination (RCE) under 37 C.F.R. 1.114 for the subject application.

By this Amendment, claims 25 and 45 have been amended to recite that an isolated Group B *Streptococcal* non-phosphorylating NADP-dependent glyceraldehyde-3-phosphate dehydrogenase is administered. Support for these amendments can be found, for example, at page 2, lines 11-15 and 27-30; page 3, lines 20-29; and page 10, lines 22-26, of the specification. Claim 45 has also been amended to recite that the isolated Group B *Streptococcal* non-phosphorylating NADP-dependent glyceraldehyde-3-phosphate dehydrogenase is administered to a subject. Support for this amendment to claim 45 can be found at page 4, lines 14-15, of the specification, which states "they may also be used in the preparation of antibodies, for passive immunization, or diagnostic applications." Claim 32 has been amended for consistency and antecedent basis.

By this Amendment, claims 47-51 have been added. Support for claim 47 can be found, for example, at page 2, lines 11-15 and 27-30; page 3, lines 20-29; and page 10, lines 18-26, of the specification. Support for claims 48-51 can be found at page 3, lines 3-5, of the specification, which states "this vaccine may be administered to females either prior to or during pregnancy to protect mother and neonate against infection by GBS."

Claims 25-29 remain rejected under 35 U.S.C. §112, first paragraph, as non-enabled by the subject specification. The applicants respectfully submit that the claimed invention is fully enabled by the subject specification.

Claim 25 recites a method for the treatment or prevention of a Group B *Streptococcal* infection comprising administering an isolated Group B *Streptococcal* non-phosphorylating NADP-

dependent glyceraldehyde-3-phosphate dehydrogenase to a patient in need of such treatment or prevention. Claim 45 recites a method for raising antibodies against Group B *Streptococcus* comprising administering an isolated non-phosphorylating NADP-dependent glyceraldehyde-3-phosphate dehydrogenase to a subject in an amount effective to produce the antibodies. Claims 37-44, which recited an immunogenic fragment of a bacterial NADP-dependent glyceraldehyde-3-phosphate dehydrogenase, have been cancelled.

The Office Action raises several issues with respect to the Declaration under 37 C.F.R. §1.132 by Joanne Moore (hereinafter, the Moore Declaration). The applicants wish to make clear that the protein used in the experiments described in the Moore Declaration was a non-phosphorylating NADP-dependent glyceraldehyde-3-phosphate dehydrogenase, having the amino acid sequence of SEQ ID NO:12. At page 3, the Office Action cites paragraph 3 of the Moore Declaration, and states that by filing the Declaration the applicants admit that testing was necessary to determine the ability of the protein to provide a protective effect upon administration. As the Examiner is aware, the teaching within the specification concerning the manner of making and using the subject invention must be taken as true unless the Patent Office can cite specific reasons to doubt the objective truth of the statements contained therein. *In re Marzocchi* 169 USPQ 367 (CCPA 1971). Furthermore, the absence of working examples within the specification is not determinative of enablement. Paragraph 3 of the Moore Declaration merely states that after the NADP-dependent glyceraldehyde-3-phosphate dehydrogenase (MS10) was identified as being located on the outer surface of GBS, the protein was tested for its ability to provide a protective effect upon GBS infection. The proteins of the invention were all selected on the basis that they had already been tested for their ability to provide a protective effect. The Declaration was filed as evidence that the application as filed enabled the claimed invention. It is well settled that, the determination of enablement must be based on evidence as a whole. The fact that the claimed invention must be enabled by the application as filed does not preclude the applicants from providing a declaration after the filing date which demonstrates that the claimed invention works (Manual of Patent Examining Procedure (MPEP) 2164.05).

The applicants respectfully submit that the experimental data in the Moore Declaration bears a reasonable correlation to the scope of the claimed methods. As indicated above, the protein used

for the experiments in the Moore Declaration was a non-phosphorylating NADP-dependent glyceraldehyde-3-phosphate dehydrogenase, having the amino acid sequence of SEQ ID NO:12. Furthermore, the applicants submit that the experiments described in the Moore Declaration are used widely by those skilled in the art to determine the vaccine potential of antigens. The experimental data presented in the Moore Declaration support both active and passive immunity as the effecter mechanisms of the immune response responsible for the observed protection.

At page 4, the Office Action raises the question as to why Table 1 of the Moore Declaration shows rat pup sacrifice. The rat pups sacrificed are those that experienced distress caused by infection. This is the normal human procedure followed for these experiments. Those that were not sacrificed were protected by the anti-sera.

An application for patent is not required to show that a claimed method of treatment of a disease condition results in a cure of that disease condition, or even that clinical efficacy is achieved. The Federal Circuit has made it clear that the showing for therapeutic utility that is sufficient to satisfy the patent laws is not to be confused or equated with the showing required by the Food & Drug Administration for drugs, medical devices, and procedures. *Scott v. Finney*, 32 USPQ2d 1115 (Fed. Cir. 1994) and MPEP 2164.05. The scope of enablement must only bear a reasonable correlation to the scope of the claims. *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970). The applicants submit the scope of enablement demonstrated reasonably correlates with the subject matter now claimed.

It is noted that claim 45, which recites a method for raising antibodies against Group B *Streptococcus*, was not included in this rejection under 35 U.S.C. §112, first paragraph, as non-enabled.

Accordingly, the applicants respectfully submit that, given the teaching of the specification, one of ordinary skill in the art could carry out the claimed methods without the need for undue experimentation. In view of the foregoing remarks, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 25, 27, 28, and 32-46 have been rejected under 35 U.S.C. §112, first paragraph, as lacking sufficient written description. The applicants respectfully submit that the subject specification provides a sufficient written description of the claimed subject matter.

As indicated above, the applicants have amended claims 25 and 45 to recite administration of an isolated Group B *Streptococcal* non-phosphorylating NADP-dependent glyceraldehyde-3-phosphate dehydrogenase. Claims 37-44, which recited an immunogenic fragment of a bacterial NADP-dependent glyceraldehyde-3-phosphate dehydrogenase, have been cancelled.

The applicants respectfully submit that those skilled in the art can readily determine which Group B *Streptococcal* proteins are non-phosphorylating NADP-dependent glyceraldehyde-3-phosphate dehydrogenases. Proteins encompassed by the recited genus would be readily envisioned by those skilled in the art. Further structural determinants are not required to identify and circumscribe the recited proteins. Thus, the applicants respectfully submit that one of ordinary skill in the art would appreciate that the applicants were in possession of the Group B *Streptococcal* non-phosphorylating glyceraldehyde-3-phosphate dehydrogenases recited in the claims as currently amended.

The applicants note that claim 32 was included in this rejection, even though the claim recites that the dehydrogenase comprises the amino acid sequence of SEQ ID NO:12. It is unclear from the disposition of the claims as to whether the Office Action is asserting that recitation of an amino acid sequence does not confer sufficient "structural features" to satisfy the written description requirement. As the Examiner is aware, each claim must be separately analyzed for compliance with the written description requirement under 35 U.S.C. §112, first paragraph. *In re Morris*, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997) and MPEP 2163 IIA1. New claim 47 also recites that the Group B *Streptococcal* non-phosphorylating NADP-dependent glyceraldehyde-3-phosphate dehydrogenase comprises SEQ ID NO:12.

The applicants respectfully submit that the subject specification conveys with reasonable clarity to those skilled in the art that the applicants were in possession of the invention as now claimed. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 45 and 46 have been rejected under 35 U.S.C. §112, first paragraph, as containing new matter. The applicants respectfully submit that claims 45 and 46 do not represent new matter.

The Office Action indicates that the textual support for claims 45 and 46 provided by the applicants does not describe a method of making antibodies. The applicants respectfully submit that

the subject specification conveys with reasonable clarity to those skilled in the art that the applicants were in possession of the claimed subject matter. At page 4, lines 11-15, the specification states:

> For example, the peptides or their active fragments may be used as antigenic determinants in a vaccine, to elicit an immune response. They may also be used in the preparation of antibodies, for passive immunization, or diagnostic applications. (emphasis added)

The supporting text for claim 45 that is relied upon by the applicants is consistent with the definition for "passive immunization" adopted at page 4, lines 21-24, of the Office Action, citing Herbert *et al.* (The Dictionary of Immunology, 4th edition, page 125, Academic Press, 1995). The Dictionary of Immunology makes clear that "passive immunity" connotes an immunity that results from an external source, such as an administered antibody from another immune individual; or, in neonates, from a maternal antibody that has passed through the placenta or been received from breast milk (see page 125, lines 6-15). At page 3, lines 3-5, the specification states "this vaccine may be administered to females either prior to or during pregnancy to protect mother and neonate against infection by GBS."

Furthermore, at page 2, lines 17-22, the specification teaches:

> The term "functional fragments" is used herein to define a part of the gene or peptide which retains the activity of the whole gene or peptide. For example, a functional fragment of the peptide may be used as an antigenic determinant, useful in a vaccine or in the production of antibodies. (emphasis added)

Clearly, blaze marks leading one of ordinary skill to the claimed invention are present in the application as originally filed. The utility of the peptides and their functional fragments to make antibodies is clearly set forth in the specification. The specification as a whole reasonably leads one skilled in the art to a method of antibody production based on administration of the recited peptide. The applicants' specification need not describe the claimed invention in *ipsis verbis*. *Ex parte Sorenson*, 3USPQ2d, 1462, 1463 (Bd. Pat. App. & Inter., 1987). The test for determining whether a claimed invention is adequately described in the specification is whether the originally filed disclosure reasonably conveys to a person of ordinary skill in the art that the applicant had possession of the subject matter claimed. *In haec verba* support is not required. The applicants respectfully submit that the subject specification conveys with reasonable clarity to those skilled in the art that the

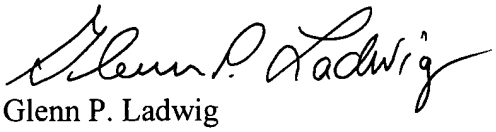
applicants were in possession of the claimed subject matter. Accordingly, in view of the foregoing remarks, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Petition and Fee for Extension of Time
Request for Continued Examination